DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/6/11 has been entered.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 23, 24, 26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109, patented Jun. 2002) in view of Manzo et al. (US 5,736,505, issued Apr. 7, 1998) and Zastrow et al. (US 5,961,988, issued Oct. 1999).

Regarding claims 17, 20, 23, 24, 26, and 30, Stora teaches perfume compositions free of organic solvents, existing in emulsified form, and capable of delivering the active agent to the skin (see abstract, in particular). Example 1 teaches a formulation comprising 2.23% perfluorodecaline, a fluorinated hydrocarbon; 24.95% Silicone DC®345, a silicone polymer; and 10.05% of a perfuming oil base; the perfluorodecaline is the oxygen carrier system as in instant claims 17 and 24. As to claim 30, Examples 3 and 4 teach a presence of 55.12% by weight of Silicone DC®345 (a silicone polymer), indicating that it is acceptable to increase the content of this silicone agent relative to the quantity used in Example 1. As to claim 31, Stora teaches topically applicable emulsions with controlled refractive indices and viscosity values. Therefore, these emulsions are formed as topically applicable lotions, creams, or gels (see column 2, lines 3-48).

Regarding claim 17, the embodiments of the invention of Stora do not illustrate a formulation having an oxygen carrier system limited to a presence between 6 and 10% by mass of the total formulation. However, it would have been within the skill of the ordinary artisan to dilute the concentration of the formulations as taught by Stora since the concentration of an oxygen carrier system in a dermatologic formulation is a result effective variable clearly affecting the type of product obtained. See MPEP 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been within the skill of the artisan to optimize the base formulation presented above prior to application in order to optimize the formulation's efficacy and minimize cost and reasonably to expect success from doing so. This dilution (i.e., in which the formulation of Stora comprises 25% (1/4)) would have involved the application of a known technique, dilution, to maximize efficacy while minimizing cost and negative side effects in order to yield predictable results since the formulation components would have retained their respective known functions upon dilution and subsequent application as a cosmetic or dermatologic formulation. It is noted that a dilution by a factor of four, for example, of Stora's formulation results in a formulation which meets the limitations of the instant claims since Stora teaches similar proportions of fluorinated hydrocarbon, silicone polymer, and oil as instantly recited. More specifically, aqueous dilution of Stora's Example 1 by a factor of four would have resulted in 0.553% by weight of perfluorodecaline, 5.93% by weight of silicone polymer, and 2.39% by weight of perfuming oil base; these values lie within the instantly recited

ranges of 0.006-1% of fluorinated hydrocarbon, 0.6-8.5% by weight of silicone polymer, and 0.3-2.5% by weight of oil base, indicating the proportional relationship between the instant claims and the known art and the predictability of the results of this dilution. Similarly, this routine optimization would have been applied further pertaining to the limitations of claims 20, 24, 26, and 30. In addition, one reasonably would have expected success from performing this dilution and subsequent optimization since Manzo et al. teaches a non-alcoholic perfume with good stability and clarity which may desirably be diluted, as is routine in the art.

More specifically, Manzo teaches water-based clear, transparent fragrance compositions having a good skin feel (see column 3, lines 25-35 and column 4, lines 2-4) and a quantity of water. The quantity of water is preferably from 50 to 80% by weight. Manzo teaches that the fragrance compositions include concentrated perfume bases which are subsequently formulated into more dilute perfume compositions (see column 4, lines 33-36). It is noted that pending claim 1 recites a formulation comprising an oxygen carrier system at 6-10% by weight of the formulation and that this claim language does not limit the quantity of water which may be considered separate from the "oxygen carrier system" which comprises an oil or water base "with a moiety of 5-25% by weight".

Both Stora and Manzo are directed to transparent perfume formulations having limited alcohol content. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform dilution of the perfume composition, within the parameters (i.e., transparency features) set forth by Stora as

suggested in the teaching of Manzo, with a reasonable expectation of success. One would have been motivated to do so to reduce the expense and chemical exposure to non-aqueous components present in the perfume formulations since Manzo teaches that fragrance compositions are often concentrated and diluted prior to application to the skin.

Stora does not specify the partial pressure of the oxygen gas in the formulation disclosed. However, Zastrow et al. teach cosmetic and dermatological formulations comprising phospholipids and fluorocarbons which together form lamellar aggregates which are loaded with oxygen, preferably up to the saturation limit. A preferred partial pressure is in the range of 10 to 40 mPa (80 to 300 mm Hg) (see column 1, lines 35 and 36; column 2, lines 25-28; column 3, lines 29-30 and lines 45-50). Similarly, Zastrow et al. teaches that perfluorinated or highly fluorinated hydrocarbon compounds are included because these compounds are desirably capable of transporting gases such as oxygen (see column 2, lines 58-61).

Both Stora and Zastrow are directed to fluorocarbon containing dermatological formulations. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to load oxygen in the fluorocarbon carrier as taught by Zastrow in the fluorocarbon carriers in the formulations of Stora. One would have been motivated to do so since Zastrow et al. teaches that a preferred oxygen pressure is up to the saturation limit, a value in the range of 80 to 300 mmHg, a range which includes the data points of the instantly recited range and where Zastrow specifies that higher oxygen content is desirable.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Manzo et al. (US 5,736,505, issued Apr. 7, 1998) and Zastrow et al. (US 5,961,988, issued Oct. 1999) as applied to claims 17, 20, 23, 24, 26, 30, and 31, and further in view of Gross et al. (US 5,637,318, (hereinafter, the '318 reference), patented Jun. 1997).

The teachings of Stora, Manzo, and Zastrow et al. are delineated above. As to claim 18, the functional limitation of oxygen content four weeks after initial loading inherently would lie within the range of 25-40% upon loading according to the instant specification. For example, page 2 of the instant specification (paragraph 5) describes the oxygen loading in which oxygen gas within a broad range of partial pressures is bubbled through the carrier system with stirring at ambient temperature for a specified time period. Upon bubbling oxygen through the carrier composition as described, the oxygen presence necessarily would result in an oxygen quantity equal to or approximating the quantity instantly claimed.

Stora do not teach a quantitative value for oxygen loading in a perfluorinated hydrocarbon carrier as in the instant claim.

Gross et al. ('318) teach oxygen-laden fluorocarbons and fluorocarbon mixtures suitable for dermatological use (see abstract, in particular). Additionally, Gross et al. state that fluorocarbons are capable of transporting oxygen (see '318 reference, column 2, line 39) and with the aid of known oxygen gas solubilities, the vapor pressure (an inherent property), and the critical solubility temperature, the loading of fluorocarbons

with oxygen can be adjusted by the skilled artisan (see '318 reference, column 4, lines 21-26).

Therefore, regarding claim 18, it would have been prima facie obvious to one of ordinary skill in the art to adjust the presence of oxygen in a fluorocarbon carrier for a dermatological application as suggested by Gross et al. in order to improve the oxygen carrying capacity of a topically applicable composition such as the one taught by Stora. One would have been motivated to do so in order to optimize the benefits associated with oxygen delivery to the skin as evaluated according to the final product. Since this optimization process would have been routine procedure, one of ordinary skill in the art at the time the invention was made would have expected resulting success.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Manzo et al. (US 5,736,505, issued Apr. 7, 1998) and Zastrow et al. (US 5,961,988, issued Oct. 1999) as applied to claims 17, 20, 23, 24, 26, 30, and 31, and further in view of Gross et al. (US 5,643,601, (hereinafter, the '601 reference), patented Jul. 1997).

The teachings of Stora, Manzo, and Zastrow are delineated above. As to claim 22, Stora teach that the perfuming ingredients can belong to a variety of chemical classes including alcohols, esters, acetates, terpenic hydrocarbons, and essential oils of natural or synthetic origin (see column 5, lines 54-60).

Regarding claim 21, Stora does not expressly include a gelling or thickening agent in the carrier system. As to claim 22, Stora does not limit the carrier system oil

base to one which is a vegetable oil, an ester, or a mixture thereof.

However, Gross et al. ('601) teach phospholipid-and fluorocarbon containing cosmetics to be formulated as gels, creams, lotions, etc. in order to supply adequate oxygen to the skin upon application (see abstract, in particular). Gross et al. teach that the fluorocarbons in this composition analogous to that of Stora can be selected for oxygen gas solubility, partial vapor pressure, and lipid solubility according to the specific intended application ('601 reference, see column 3, lines 28-30). Specifically, Gross names perfluorodecalin as a rapid release oxygen carrier which also is embodied in the invention (see '601 reference, column 3, line 34; see also, column 4, Table 1). As to claim 21, Gross et al. teach the inclusion of hydroxyethyl cellulose (a thickening agent), in a gel mask formulation of the invention (see '601 reference, column 7, example 9). As to claim 22, Gross et al. teach jojoba oil and liquid paraffin as components in Example 5, a body lotion. One of ordinary skill in the art at the time of the invention would have recognized that jojoba oil is a liquid wax produced in the seed of the jojoba plant and is a mixture of wax esters desirably present in cosmetic and topical applications.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stora and Gross et al. in order to maintain the benefits of the fluorocarbon formulation component (i.e., optimized oxygen incorporation and delivery) and to further optimize this oxygen carrier component in the analogous product resulting from this combination of teachings. The skilled artisan would have been motivated to optimize physical properties such as

formulation thickness and therefore manageability by including a known gelling agent such as hydroxyethyl cellulose as is routine in the cosmetic arts and as is suggested in the disclosure of Gross et al., particularly since Gross et al. state a variety of cosmetically acceptable formulations such as gels, pastes, ointments, creams, lotions, etc (see '601 reference, column 4, lines 10-11). Similarly, the artisan would have been motivated to implement jojoba oil into the topically applicable formulations on account of its commonly recognized and desirable properties such as being odorless and relatively shelf-stable when compared with other vegetable oils useful as cosmetic carriers, as taught by Gross et al.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Manzo et al. (US 5,736,505, issued Apr. 7, 1998) and Zastrow et al. (US 5,961,988, issued Oct. 1999), and Gross et al. (US 5,643,601) as applied to claims 17, 20, 23, 24, 26, 30, and 31 above and further in view of Pelle et al. (US 5, 811,083, patented Sep. 1998), and Nakanishi et al. (US 6,576,623 B1, patented Jun. 2003).

The teachings of Stora, Manzo, Zastrow, and Gross are delineated above. Stora does not disclose the inclusion of tocopherol or a tocopherol derivative in the instantly prescribed quantity. It is noted that Gross et al. teach the inclusion of antioxidants such as a- tocopherol (see '601 reference, column 3, lines 66-67) in analogous perfluorodecalin-containing cosmetic compositions.

However, these references do not teach the instantly specified tocopherol derivatives in the instantly specified quantity. Nakanishi et al. teach silicone compounds useful in cosmetic applications wherein tocopheryl succinate is taught as a functional equivalent to a-tocopherol (see column 10, lines 58-60), and Pelle et al. specifically teach tocopherol derivatives for use in cosmetic compositions. Specifically, Pelle et al. disclose advantages of using tocopherol derivatives for regulating skin aging and other disorders and suggest a most preferred quantity of 0.01 to 1.0 wt. % for topical applications (see column 7, lines 32-36). Further, one of ordinary skill would have been motivated to optimize this formulation component presence in order to impart desired properties to the final product. MPEP 2144.05 addresses the patentability of routine optimization procedures as addressed above.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute tocopheryl succinate as taught by Nakanishi for the a-tocopherol disclosed in the formulations of Gross et al. One would have been motivated to do so since these a-tocopherol and tocopheryl succinate have been shown in the prior art to be interchangeable and to have insubstantial differences both structurally and functionally. Likewise, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Pelle et al. with the teachings of Gross et al. in order to determine a desirable quantity of tocopherol derivative in a cosmetic formulation. Also, it would have been prima facie obvious to combine the teachings of Gross et al. and Stora and to utilize Gross' suggestion to include tocopherol or its derivative in a topically applicable

perfluorodecalin-containing cosmetic composition. One would have been motivated to combine these teachings since Gross et al. teaches the advantage of avoiding auto-oxidation processes in other formulation components by adding an anti-oxidant such as alpha-tocopherol to a formulation analogous to that of Stora. Since Gross et al. does not specify an acceptable quantity, the artisan would have been motivated to look to Pelle et al. in order to determine a topically acceptable quantity of the tocopherol agent.

Response to Arguments

Applicant's arguments presented 9/6/2011 have been fully considered. Applicant's positions against cited references are summarized and responded to as follows.

Regarding the issue of dilution and normalization, the Examiner thanks Applicant for clarifying what calculations Applicant used to arrive at the normalized values, and these calculation are accepted.

Applicant takes the position that the proposed dilution renders the prior art composition of Stora unsatisfactory for its intended purpose because the addition of water through an aqueous dilution is said to substantially change the formulation's refractive index and that the secondary references cure this alleged deficiency. As a justification for this position, Applicant presents a declaration under 37 CFR 1.132 from Inventor Karen Golz-Berner. This declaration shows results of a test comparing Stora's Example 1 and a fivefold dilution thereof. Inventor Golz-Berner's data shows that the difference in refractive index of the oily and aqueous phase of Stora's Example 1 is

0.0016 and that the diluted example has a difference in refractive index of 0.00417 and is not transparent. Applicant then concludes that Stora would have been rendered unsuitable for its intended use as a transparent perfume composition.

In reply, Applicant's argument that the five-fold dilution, which was proposed as a suggested example of an acceptable modification to the Stora teaching, is unacceptable is persuasive because Inventor Golz-Berner's declaration shows the results of a five-fold dilution of Example 1 to have a refractive index above the acceptable threshold taught by Stora. Although Applicant's argument against the proposed five-fold dilution is persuasive, Applicant's remarks are not sufficient to overcome the rejection of record. It is clarified that the proposed five-fold dilution was merely an illustrative example, and that since it has been shown to be inconsistent with Stora's teaching of a refractive index upper limit of 0.003, the rejection is maintained since it would have been within the skill of the ordinary artisan to adjust the dilution so as to utilize the known benefits and properties taught by Stora by performing dilutions within the parameters (i.e., difference in refractive indices) of Stora. The grounds of rejection above have been changed to suggest a four-fold dilution of Stora's example 1 rather than a five-fold dilution; this change maintains consistency with the teaching of Stora while utilizing the skill of the ordinary artisan to optimize the presence of each formulation component. It is maintained that dilution technique and subsequent refractive index measurements would have been within the skill of the ordinary artisan, as suggested by the declaration of Inventor Golz-Berner. For these reasons, Applicant's arguments and declaration are unpersuasive against the rejection of record. Nonetheless, the Manzo reference has

been newly cited to provide a particular motivation for performing dilution of a concentrated perfume base, thereby strengthening the case of obviousness, and for this reason, the instant rejection is non-final.

Conclusion

No claims are found allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/RICHARD SCHNIZER/
Primary Examiner, Art Unit 1635